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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,369	04/13/2004	Marc Richelsoph	2184.00091	4869

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EXAMINER

STOKES, CANDICE CAPRI

ART UNIT PAPER NUMBER

3732

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/823,369

Applicant(s)

RICHELSOPH, MARC

Examiner

Candice C. Stokes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21,23-28 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21,23-25,27,28 and 31 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04/13/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference numerals 34 and 36. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: in line 19 "rodseating means" should be "rod seating means". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 31 recite the limitation a “rod seating means operatively engaged with said fixing means for seating a rod therein including at least one flexible portion capable of being compressed against a rod seated within said rod seating means, wherein said at least one flexible portion has a tapered outer surface end; and locking means for securing and engaging the rod and rod seating means including at least one flexible portion, said locking means including deflecting”(see lines 13-18 of Claim 1 and lines 7-11 of Claim 31). Further the Specification discloses “the locking mechanism 36 engages the rod 16 and the rod seating mechanism 28. The locking mechanism 36 includes a deflecting mechanism 38 for deflecting at least one flexible portion 46 of the rod seating mechanism 28 against and around the rod 16”(see page 14, lines 22-25). It is unclear whether Applicant is attempting to claim the locking means having a flexible portion or if they are referring to the flexible portion of the rod seating means as supported in the Specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,9-14,16-21,23,27-28 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Richelsoph (USPN 5,964,760). Richelsoph discloses a screw and rod fixation assembly comprising a screw 12” with a screw head 40 having fixing means comprising insert 70 and body 30””. The insert 70 includes an inner passageway for fixing the screw 12” from movement relative to the assembly. The fixing means can both automatically and compressively fix screw 12” from movement. As Richelsoph explains “once the screw head 40”” is fully inserted into the pocket, the insert 70 snaps onto the screw head 40””. In this condition, polyaxial movement can be achieved. Locking can be achieved in two manners. The body 30”” can be pulled up relative to the screw 12”” with an instrument (not shown) without the rod 20”” being in place or pulled by the nut 26”” as the nut 26”” is tightened over the rod 20””. This provides the surgeon with the option of adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20”” to the assembly 10”” or locking the screw 12”” and the rod 20”” interfaces simultaneously when correction is not required” (col.8, lines 23-31). The insert 70 of the fixing means, which is a substantially annular ring including an edge portion extending about a center axis and having a frustoconical surface tapering outwardly toward the edge portion for engaging the screw head 40”” while allowing a portion of the screw 12” to pass therethrough as shown in Fig. 7, having an inner surface wall having a gripping portion and a

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non-gripping portion. Rod seating means 16''' is operatively engaged with the fixing means for seating a rod therein. Because Richelsoph discloses the body 30''' can be pulled by nut 26''' which is used to tighten over rod 20''' by bringing the arms of the rod seating means together, it is inherent that there is at least some flexibility in the rod seating means. This also reads on claim 6. Locking means 22 comprising nut 26''' is for securing and engaging the rod and rod seating means. This also anticipates Claims 23,27-28 and 31. As to Claims 2 and 3, rod receiving means 16''', it includes a body portion 30''' having two arms 24''',14''' extending therefrom and being substantially parallel relative to each other. The two arms 24''',14''' and the body portion 30''' form a U-shaped inner surface defining the seat portion thereof. Regarding As to Claims 9-11 and 17-18, the fixing means 14'' includes an inner surface wall 44 having a gripping portion. Further, "the rod seating member 14'' is then disposed over the head portion 40 of the screw element 12'' by insertion of the head portion 40 into the seat 44. This is a snapping operation but allows for angular adjustment of the tubular member 14'''(col. 6, lines 30-33). Regarding Claims 12-13 and 19, the substantially tubular body has spaced parallel arms as shown in Fig. 5. As to Claim 14, inner surface 44 has an aperture. With regard to Claim 16, "the fixing means 70 is sufficiently collapsible to be snapped into the internal portion 72 of the body element 34''. This is accomplished by compressing the fixing means 70 and releasing it inside the internal portion 72. The assembly itself can be made from any durable material, such as carbon composites, nitinol, stainless steel, composite materials, plastics, and plastic compositions" (col.7, lines 65-67 & col8, lines 1-5). As to Claims 20-21, Richelsoph discloses rod seating means 70 with a top portion as shown in Fig. 9 considered to be a body portion with a tapered flexible portion 80 extending therefrom.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,7-8,15, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richelsoph in view of Schlapfer et al (USPN 5,520,689). Richelsoph discloses the claimed invention except for the locking means being a set screw with a threaded outer surface. Schlapfer et al teaches a set screw 7 with a threaded outer surface 12, which engages the threaded inner surface 11. As to Claims 8 and 25, Richelsoph discloses “in this manner as the locking mechanism 22 forces the inner wall 18 to contour around and engage the rod 20 seated therein” (col. 3, lines 46-49). The embodiment as shown in Fig. 8 of Richelsoph functions in the same manner. The Schlapfer et al patent shows that the same function will be performed if the threads of the rod seating means disclosed by Richelsoph were on the inner portion of the arms and a locking screw with threads on its outer portion were used to engage the rod into the seating means. It would have been obvious to one having ordinary skill in the art to incorporate the threaded outer and inner surfaces as taught by Schlapfer et al into the screw and rod fixation assembly disclosed by Richelsoph, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art (*In re Einstein*, 8 USPQ 167), and further in order to provide a more secure engagement between the locking member and the rod seating means.

*Allowable Subject Matter*

Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*

Applicant's arguments filed 10/20/05 have been fully considered but they are not persuasive. For clarification purposes, the rejection has been slightly modified. The arguments submitted by Applicant as to the fixing means being automatically and compressively fixing a screw from movement relative to the assembly has been further addressed in the modified rejection. Specifically the rejection asserts that the Richelsoph patent discloses the screw being automatically and compressively fixed by the fixing means. As stated in the rejection, Richelsoph explains "once the screw head 40"" is fully inserted into the pocket, the insert 70 snaps onto the screw head 40"". In this condition, polyaxial movement can be achieved. Locking can be achieved in two manners. The body 30"" can be pulled up relative to the screw 12"" with an instrument (not shown) without the rod 20"" being in place or pulled by the nut 26"" as the nut 26"" is tightened over the rod 20"". This provides the surgeon with the option of adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20"" to the assembly 10"" or locking the screw 12"" and the rod 20"" interfaces simultaneously when correction is not required" (col.8, lines 23-31). Therefore, the fixing means can be automatically fixed as when nut 26"" is not used or compressively as when it is unnecessary to use the nut. Therefore, Claims 1-21,23-25,27,28, and 31 remain rejected.




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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Candice C. Stokes

  
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